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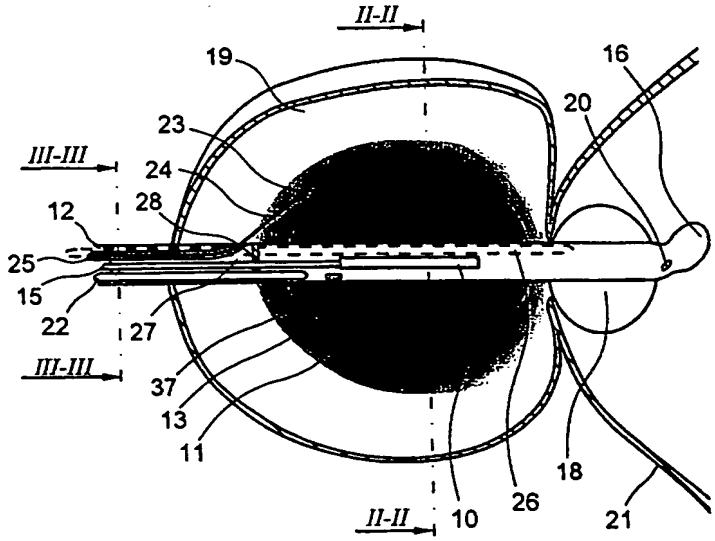

(57) Abstract

A device for heat treatment of body tissue, comprising a treatment catheter (12) having an expandable fluid container (11) and a heating element (10) arranged within said container (11). The heating element (10) comprises means for emitting electromagnetic radiation for heating the fluid within the fluid container (11) and body tissue surrounding the liquid container (11). The invention also includes a method for the treatment of prostate tissue (19), electromagnetic radiation being emitted from said heating element (10) for heating fluid in the fluid container (11) and body tissue surrounding the liquid container (11).

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METHOD AND DEVICE FOR A COMBINED HEAT TREATMENT OF BODY TISSUE

Technical Field

The invention relates to a method and a device for heat treatment of body tissue according to claim 1 and 10, respectively.

In some cases of illness in which there is an enlarged growth of body tissue a good result of treatment can be achieved by heat treatment. The body tissue is heated to such an extent that there is a necrosis of the tissue. Examples of such cases of illness are some kinds of cancer and Benign Prostatic Hypertrophy, BPH. During treatment some parts of the tissue are heated to obtain necrosis while other parts have to or should be protected. In this respect it is in the first place cases of illness existing in tissues surrounding cavities in the body that are of interest. Besides the examples given above also cancer in the oesophagus, trachea, ureter and intestine can be mentioned.

Corresponding illnesses may appear also with animals and a corresponding treatment can be introduced. Preferably a treatment of pets, such as dogs, may come into question.

Prior Art

It is possible to use different types of devices to achieve the temperature raise. Devices for laser heating as well as devices for microwave and radio frequency heating are commonly used. From US-A-5257977 it is known to provide a treatment catheter with a liquid container. The container is flexible and is connected through channels within the catheter to a heating element arranged outside the body and outside the catheter. A liquid is heated by the heating element and is circulated through the channels and the container, which to some extent is expanded for a better engagement with the tissue. The temperature raise in the container will also lead to a heating of any surrounding tissue. The treatment is affected by a control of the temperature of the circulating liquid.

While the channels extends along tissue sections that are not to be treated they have to be heat insulated. According to US-A-5257977 the heat insulation is obtained by gas filled spaces extending around the channels. The function of the heat insulation is very important and a large attention and considerable costs are spent on this part of the treatment catheter. Another disadvantage with the device according to US-A-5257977 is that it is difficult to achieve a desired control of the temperature because the distance between the heating element and the treatment area is comparatively large.

A further developed treatment catheter is disclosed in WO 97/02794, according to which a heating element is provided within an expandable container. The heating element is energised by means outside the body for heating the liquid within the container. Some of the disadvantages of an undesired heating of parts of the tissue may thus be avoided. According to WO 97/02794 the heating element is formed as a resistance wire or the like and will heat the liquid by convection. The heat that is transferred from the liquid to the surrounding tissue will provide a good result locally. A disadvantage is that the effect on tissue parts at a larger distance from the container will be insignificant.

Summary of the Invention

An object of the invention is to increase the treatment efficiency of prior art treatment catheters while at the same time decreasing the risk of an incorrect treatment. The increased treatment efficiency will allow shortened treatment sessions. This object has been achieved by the invention as claimed in claim 1 and claim 10, respectively.

The treatment efficiency will be increased because a treatment device according to the invention comprises means for compressing prostate tissue and means for heating the compressed tissue as well as more distant tissue. As a result the level of power that is supplied to the treatment device can be decreased leading to an increased safety for the patient and a lower risk of treatment damages as a result of a high power usage.

Further advantages and features of the invention will be clear in the light of the following description, drawings and dependent claims.

Brief description of the drawings

The invention will now be described in further detail with reference to a preferred embodiment shown in the accompanying drawings, in which

FIG 1 is a longitudinal sectional view from line *I-I* in FIG 2 of one embodiment of a treatment catheter according to the invention,

FIG 2 is a transversal section of the prostate along line *II-II* in FIG 1 and a treatment catheter inserted therein,

FIG 3 is a cross sectional view from line *III-III* in FIG 1, and

FIG 4 is a schematic block diagram showing a treatment catheter included in a treatment apparatus.

Detailed description of the invention

In the embodiment shown in FIG 1 a fluid container 11 is arranged on the outside of a treatment catheter 12. Said treatment catheter is mainly intended for the treatment of prostate tissue. Said fluid container 11 is flexible and according to FIG 1 expanded by a fluid 13 introduced therein at an overpressure. When the fluid 13 is introduced in the container 11 urethra is filled by the expanded container 11 to start with. Then the prostate will be dilated. The engagement between the container 11 and the prostate tissue will be excellent. The complete filling and the excellent engagement will also result in further advantages as shown below.

A heating element 10 is provided within the fluid container 11 for heating the fluid 13. Instead of a conventional type heating element there is used a heating element 10 according to the invention which will emit electromagnetic radiation, preferably microwaves, but also laser and other types of light may come into use. The energy delivered by the heating element 10 will to some extent be absorbed by the fluid, which in a preferred

embodiment of the invention comprises water or a salt solution, and to some extent according to the invention the energy will be emitted into the surrounding tissue. Energy will be provided through a feeding cable 15 from a power supply unit 14 (see FIG 3).

The treatment catheter 12 according to FIG 1 is inserted through urethra to such an extent that a tip 16 enters into the urinary bladder 21. A bladder or balloon 18 connected to the treatment catheter is expanded within the urinary bladder 21 and will prevent an unintentional withdrawal of the treatment catheter during a treatment session. Thereby the active part of the treatment catheter is located centrally in the tissue intended for treatment, in this case the prostate 19. The treatment catheter 12 is flexible and ductile, so as to be readily inserted through urethra into a working position.

In FIG 1 the container 11 is expanded to a working volume by introducing a fluid therein at an overpressure. The container 11 will thereby be spool-shaped with a larger length along the treatment catheter. This shape adapts to or will be adjusted to the shape of urethra in this part. The container 11 is arranged on the treatment catheter and a larger part of the container 11 is formed on the underside of the treatment catheter. Thus when the container 11 is expanded the treatment catheter will be lifted which in the body will increase the distance between the heating element 10 and rectum. The fluid will be provided through a channel 22 formed as a tube extending through the treatment catheter 12 (see also FIG 4). The expansion of the container 11 will also cause a compression of prostate tissue around urethra and provide an excellent engagement to urethra. When the tissue is compressed also blood vessels in the tissue are compressed, which will result in a decreased blood flow and thereby in a decreased cooling caused by the body. As a result during a session an efficient heating of the tissue will be achieved also with a comparatively low power of the heating element 10. The efficient heating will cause a massive necrosis in the vicinity of the treatment catheter. When the heating element 10 comprises a microwave antenna, which delivers energy to body tissue also at a larger distance from

the microwave antenna, heating will be achieved also in such a remote body tissue.

To be able to monitor the temperature development in the tissue a temperature sensor 23 is provided on a carrier 24. The carrier 24 is arranged slidable through a channel or tubing 25 extending through the treatment catheter. Preferably the carrier 24 or the temperature sensor 23 is formed with or as a tip that can penetrate a membrane or wall of the treatment catheter as well as body tissue. The tubing 25 is formed so that the carrier 24 together with the temperature sensor23 will be extended out of the treatment catheter at an appropriate angle and can be driven out to an appropriate distance from the treatment catheter. It is possible also to provide a separate inclined means in the end part of the tubing 25 so as to accomplish the desired inclination of the temperature sensor 23. A second temperature sensor 37 can be provided in the treatment catheter 12 within the container 11 and preferably in heat conducting position to the container 11.

The treatment catheter also comprises a liquid channel 26 opening in the balloon 18 and through which liquid can be provided for expanding the balloon 18 when the treatment catheter is located correctly. The liquid channel 26 is used also to drain the balloon 18 after a completed session and before the treatment catheter again is withdrawn from urethra. Preferably, a conventional syringe or a similar device is used for the filling and draining of the balloon 18.

The feeding cable 15, through which the heating element 10 is provided with energy, will be heated as a result of heat losses. To avoid damages in tissues outside the treatment area, for instance in the sphincter enclosing urethra below the prostate, the feeding cable 15 is cooled. The cooling is achieved by cooling channels 27 in the treatment catheter 12 (see also FIG 4), preferably in the area around the feeding cable 15. Said cooling channels 27 comprise in one embodiment according to the invention an end wall 28 by which a coolant that is circulated in the cooling channels is returned. It is thereby possible to avoid a cooling of the heating element 10

per se in turn resulting in a decreased power level of the energy that has to be provided from the unit 14. Lower levels of power also limits the risks for an incorrect treatment and damages of healthy tissues.

Thus, the heating of tissue is performed partly at a short distance by heating the fluid contained in the container that will deliver heat directly to any adjacent tissue, and partly at a larger distance by the electromagnetic radiation. The total area of treatment will be increased as compared to a conventional heating process and thus larger sections of tissue can be reached.

The fluid 13 within the container is heated by the heating element 10 to such a temperature that surrounding tissue will be heated to approximately 60°C. At this temperature a treatment session will last for approximately 1 hour. Depending on the size of the treated area and the treatment temperature chosen the treatment session can be longer or shorter. By rising the treatment temperature to be within the interval of 90-150°C the treatment session can be shortened to a few minutes, such as 5 minutes. At such high temperatures the tissue will also be hardened and will form a shell. While the highest temperature will be reached in the tissue adjacent to the container 11 that part of urethra which passes through prostate in the treatment area will be affected to a high extent and will be destroyed. However, this part of urethra will regenerate within a comparatively short period of time.

In a preferred embodiment the heating element 10 comprises a microwave antenna. While urethra is completely filled up in the treatment area and there is no free space left also the microwave antenna adaptation to the tissue will be excellent. The fluid in the container 11 is chosen so as to essentially or completely have the same characteristics as prostate tissue with regard to microwave propagation. As a result also the impedance match between the antenna and the tissue will be excellent, which in turn will facilitate the design of the antenna and the power supply unit and will facilitate a control of the microwave effect.

When the treatment has come to an end the power supply to the heating element 10 is stopped, and the container may return to a normal

body temperature. It is inappropriate to withdraw the treatment catheter as long as the container still has a temperature that may cause damages during passage of the container through the body. For this reason the temperature of the container 11 continuously is monitored and the treatment catheter will be withdrawn as soon as the required temperature has been reached.

In those cases where the treatment concerns the prostate or the urinary bladder and the catheter 12 is inserted in the urethra with a tip inside the urinary bladder 21 there can be a drainage of urine and possible other fluids from the urinary bladder through a drainage channel formed in the catheter 12. The drainage channel extends through the complete catheter 12 and opens with an opening 20 close to the tip of the catheter. For some types of treatment it can be convenient to leave the catheter 12 in place for some time after the treatment session. Also during this period of time the function of the drainage channel is to drain the urinary bladder.

As soon as urine again may pass through urethra in the prostate the treated and destroyed tissue will be carried with the urine. A remaining cavity in the prostate left after the removed tissue will ensure an appropriate passage of urine. Initially the cavity will have a shape that corresponds to the shape of the container 11 during the treatment session, that is with a larger cross section area adjacent to the urinary bladder 21.

As a complement to or a part of the heat treatment as described above some kind of drug can be introduced in the fluid container 11. In those cases the fluid container 11 is modified to allow a passage of the drug. Preferably the fluid container 11 is designed to allow the drug to diffuse through a wall of the fluid container 11, but it is possible also to form leakage channels or similar apertures in the wall. In one form of treatment an analgesic can be included in the fluid. Also other drugs having a direct effect on the treatment can be used.

FIG 2 shows diagrammatically the propagation characteristics from the microwave antenna 10 and the fluid container 11. Different levels of energy from the microwave antenna 10 are shown with dashed lines. A first energy level L_1 covers the area adjacent to the microwave antenna 10 and mainly

the fluid container 11. At the level L_1 there is an efficient heating of the fluid 13 in the fluid container 11. The propagation of radiation energy from the microwave antenna 10 extends through the prostate 19 at a decreasing intensity level. At an energy level of L_2 there still is an adequate effect of treatment with necrosis, while the effect of treatment an the energy level of L_3 is weak. In the area defined by line *H* the short range heating from the container 11 is predominant. The line *H* defines an area 29 in which an excellent effect of treatment is achieved. In the area 29 the tissue temperature can be raised to such an extent that the tissue hardens to form a shell, particularly as the prostate tissue adjacent to the expanded fluid container 11 to some extent is compressed. The compressed prostate tissue will also require a lower power level, because a lower part of the heat is dissipated by the blood flow.

FIG 3 shows diagrammatically one embodiment of a treatment catheter 12. The treatment catheter 12 is formed with a plurality of cavities and channels extending along the treatment catheter. The feeding cable extends in a central cavity 30. A coolant is conveyed through four cooling channels 27 separated by intermediate walls 31, preferably in a circulating system. The tubing 25 is arranged in a first cooling channel 27. In a corresponding way the fluid channel 26 for the balloon 18 and the channel 22 for the fluid container 11 are arranged in further cooling channels 27. Also a drainage channel opening at 20 in the treatment catheter can be arranged in a similar way in a cooling channel.

The block diagram of FIG 4 shows schematically different functional blocks that may be included in a treatment apparatus with a treatment catheter according to the invention. As mentioned above the heating element 10 is supplied with energy from a power supply unit 14. A central control unit 32 is operatively connected to the power supply unit 14 and a display unit 33 and also to a pump and cooling device 34 and a fluid supply unit 35. The control unit 32 also is operatively connected to an input means, for instance a keyboard 36. The control unit 32, the keyboard 36 and the display unit 33 can also be parts of a conventional computer with a monitor and a keyboard.

The control unit 32 is operatively connected to the temperature sensors 23 and 37 and can in dependence of the present temperature in the treated area control the power supply unit 14, so as to supply the appropriate level of power to the heating element 10. In this way it will be possible also to raise the temperature of the fluid container 11 and also in the surrounding tissue at a satisfying safety level to produce an intended destruction of the tissue. Information regarding the temperature from the temperature sensors 23 and 37 also can be shown on the display unit 33.

The pump and cooling device 34 is connected to the cooling channels 27 and will pump an appropriate coolant through the cooling channels 27 to cool mainly the feeding cable 15 where it extends up to the heating element 10. The fluid supply unit 35 is used when the fluid container 11 is filled and expanded. The filling procedure is monitored by the control unit 32 so as to accomplish an appropriate raise of pressure and compression of prostate tissue.

The container 11 is completely sealed and encloses a volume of fluid 13 having appropriate heat conducting properties. Examples of such fluids are silicone oil and water. The container 11 is made of elastic silicone or another material having corresponding elastic properties, such as latex. Also the treatment catheter 12 can be formed of silicone or a similar material as may the bladder 18.

CLAIMS

1. A device for heat treatment of body tissue, comprising a treatment catheter (12) having an expandable fluid container (11) and a heating element (10) provided within the fluid container (11), *characterised* in that the heating element (10) comprises means for emitting electromagnetic radiation for heating fluid in the fluid container (11) and body tissue surrounding the fluid container (11).

2. A device as claimed in claim 1, wherein a first temperature sensor (23) is arranged to be extended from the treatment catheter (12) into the heated body tissue.

3. A device as claimed in claim 1, wherein the heating element (10) comprises a microwave antenna that is power supplied by a power supply unit (14) through a feeding cable (15) that is extended through the treatment catheter (12).

4. A device as claimed in claim 3, wherein cooling means (27) are arranged for cooling the feeding cable (15).

5. A device as claimed in claim 4, wherein said cooling means (27) comprise cooling channels extending in the longitudinal direction of the treatment catheter (12), a coolant being circulated through said cooling channels.

6. A device as claimed in claim 5, wherein an end wall (28) is provided in the treatment catheter (12), so as to limit the circulation of the coolant to a section of the treatment catheter (12) completed before said heating element (10).

7. A device as claimed in claim 1 for treating prostate tissue (19), comprising treatment catheter (12) that is inserted through urethra to such an extent that

a catheter tip (16) extends into the urinary bladder (21), wherein said fluid container (11) is provided on the outside of the treatment catheter (12) and in a expanded condition will compress the prostate tissue (19).

8. A device as claimed in claim 1, wherein said fluid container (11) holds a drug and is formed to allow emission of the drug through a wall enclosing the fluid container (11) to surrounding tissue.

9. A device as claimed in claim 8, wherein the wall of the fluid container (11) is formed to allow diffusion of the drug to surrounding tissue.

10. A method for treating prostate tissue (19) with a treatment catheter (12) having an expandable fluid container (11) and a heating element (10) provided within the fluid container (11), *characterised* by

emitting electromagnetic radiation from the heating element (10) for heating fluid in the fluid container (11) and body tissue surrounding the fluid container (11).

11. A method as claimed in claim 10, wherein the temperature continuously is measured in the treated body tissue and the measured temperature is used for controlling the power level supplied to the heating element (10).

12. A method as claimed in claim 10, wherein a drug is supplied to the fluid container (11) to be administered through a wall enclosing the fluid container (11) into surrounding tissue.

13. A method as claimed in claim 12, wherein the drug is diffused through the wall of the fluid container (11).

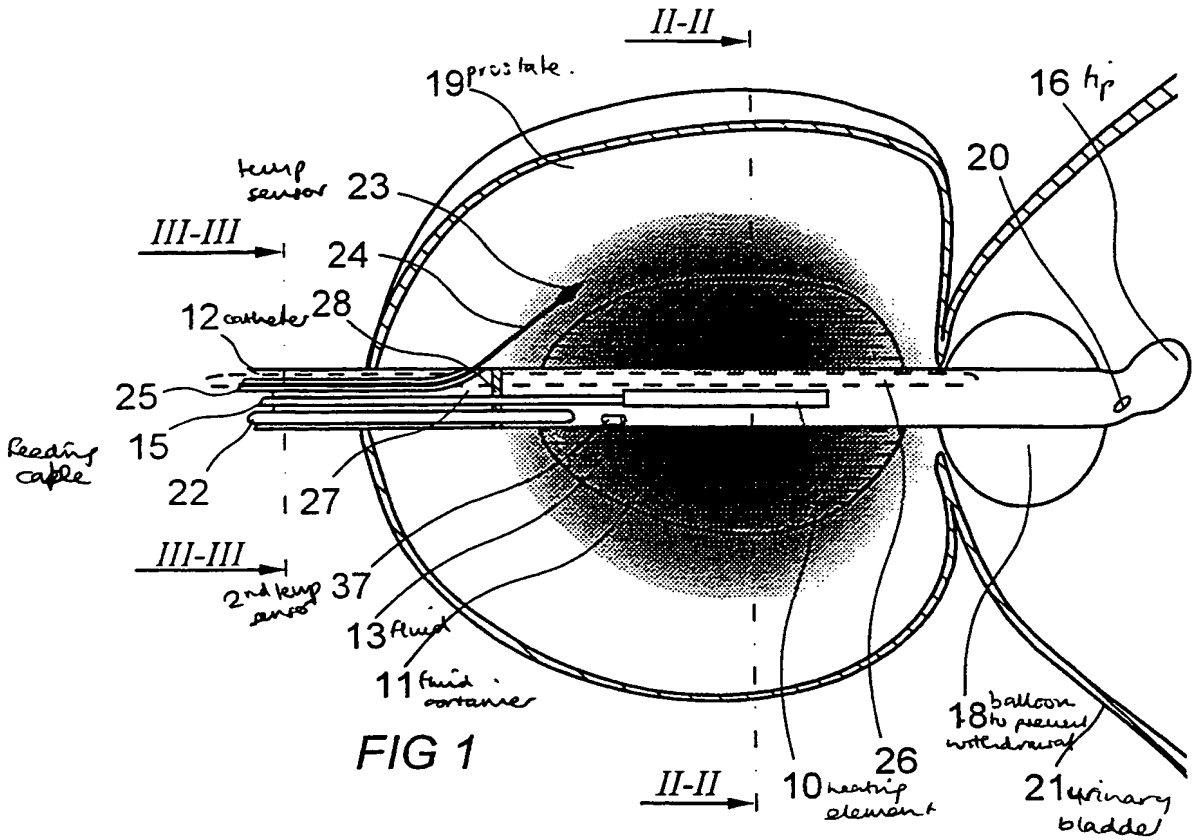

FIG 1

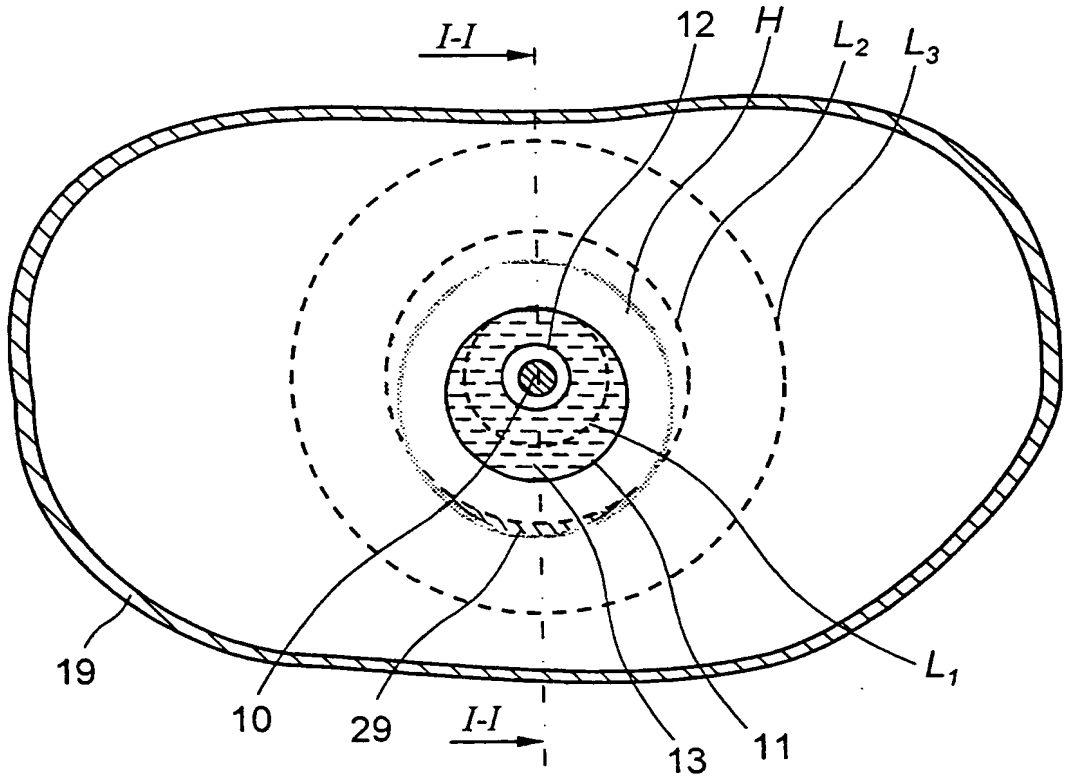

FIG 2

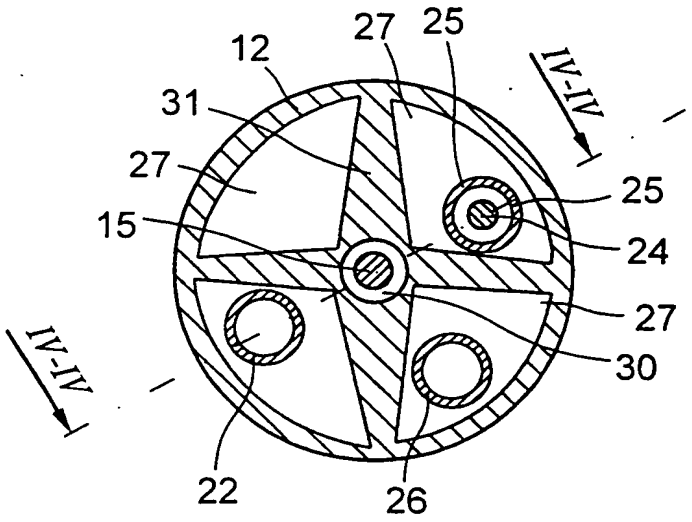

FIG 3

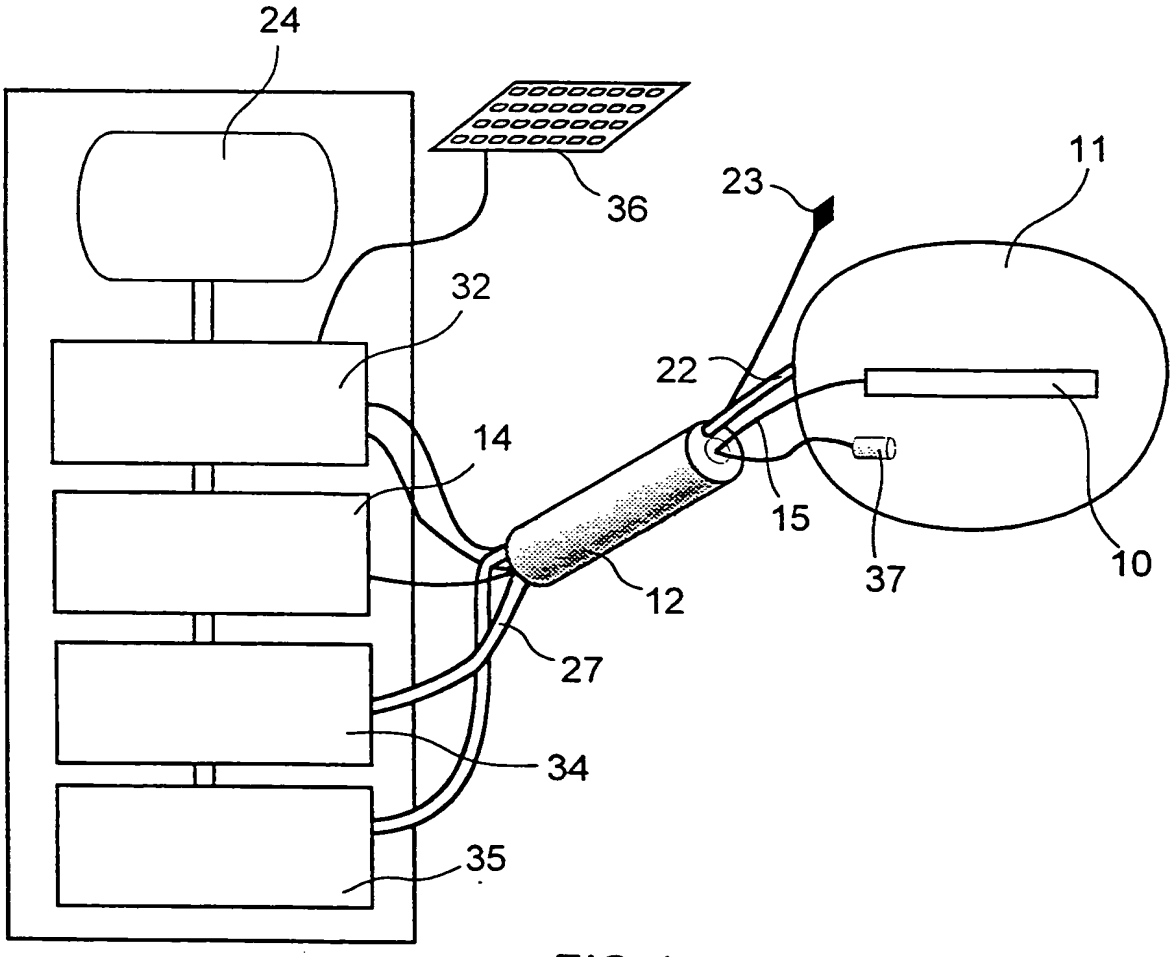

FIG 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 98/01417

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 7/12
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9117731 A1 (WAYNE STATE UNIVERSITY), 28 November 1991 (28.11.91), page 7, line 29 - page 11, line 2	1,3
X	WO 9309724 A1 (FONDAZIONE CENTRO SAN ROMANELLO DEL MONTE TABOR), 27 May 1993 (27.05.93), page 3, line 24 - line 5; page 7	1,3
X	US 4979948 A (LESLIE A. GEDDES ET AL.), 25 December 1990 (25.12.90), column 3, line 28 - line 49	1,3

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"P" document published prior to the international filing date but later than the priority date claimed
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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an invenuve step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 January 1999	
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Anette Hall Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 98/01417

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 10-13
because they relate to subject matter not required to be searched by this Authority, namely:

A method of treatment of the human or animal body by surgery or therapy (Article 17(2)(a)(i) and Rule 39.1(iv)).

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See additional sheet.

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1 and 3

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 98/01417

A

a) Claim 2: A device for measuring temperature.

b) Claims 4-6: A cooling device.

c) Claim 7: A balloon catheter/dilator.

d) Claims 8-9: A balloon catheter for introducing remedies.

B

In the light of WO, 91/17731,A1; WO, 93/09724, A1 or US, 4 979 948, A the subject-matter of claim 1 lacks novelty. Document WO, 91/17731,A1 further discloses the details according to claim 3.

The features of dependent claims 2, 4-9 are of such nature that they define subject-matter without any technical relationship between them.

Since the common concept represented by claim 1 is not new and there cannot be found a technical relationship involving corresponding special technical features, under Rule 13.2, between the subject-matter of claims 2, 4-9, i.e. inventions a) to d), these inventions, a) to d) are not linked together by a single common inventive concept.

Consequently, the claims represent at least four different inventions, a) to d).

a) Claim 2: A device for measuring temperature.

b) Claims 4-6: A cooling device.

c) Claim 7: A balloon catheter/dilator.

d) Claims 8-9: A balloon catheter for introducing remedies.

For the search report, only the invention first mentioned in the claims has been searched, i.e. claims 1 and 3.

INTERNATIONAL SEARCH REPORT

Information on patent family members

01/12/98

International application No.
PCT/SE 98/01417

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